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EXAMINER

SANDALS, WILLIAM O

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/708,276

Applicant(s)
Nabel

Examiner
William Sandals

Art Unit
1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 2, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-41 is/are pending in the application.
- 4a) Of the above, claim(s) 2-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

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DETAILED ACTION

Election/Restriction

1. Claims 2-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention of Groups I-V, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5, mailed January 2, 2002.
2. Applicant's election without traverse of Group VI, claims 29-41 in Paper No. 5 is acknowledged.

Drawings

3. The drawings as submitted on November 7, 2000, have been approved by the draftsman.

Specification

4. The disclosure is objected to because of the following informalities: New matter has been added to the specification at page 7, and the Brief Description of the Figures is improper.
5. The amendment filed January 22, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: at page 7, line 16 has been amended to read "therapeutically effective".

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Applicant is required to cancel the new matter in the reply to this Office action.

6. The Brief Description of the Figures recites "Figure 2A", Figure 3A and Figure 4A as headings for each of the respective figures. The headings for the figures should be amended to read, for example "Figures 2A-C".

Correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 29 and 32-35 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,110,744.

US 6,110,744 taught (see especially columns 3, 18, 19, 29 and claim 23) a composition comprising a nucleic acid encoding p27 gene and a catheter. The nucleic acid is contained in a viral particle expression vector, and the composition may also comprise a liposome. The expression vector may comprise a second gene. The limitation of a "kit" in the preamble of claim 29 connotes nothing more than a collection of items, and US 6,110,744 taught the instant claimed collection of a nucleic acid encoding p27 gene and a catheter for the practice of the invention as taught by US 6,110,744.

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9. Claims 29, 32-35, 39 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,672,508.

US 5,672,508 taught (see especially columns 7, 815, 20 and 21) a composition comprising a nucleic acid encoding p27 gene and a catheter. The nucleic acid is contained in a viral particle expression vector, and the composition may also comprise a liposome. The expression vector may comprise a second gene which may be a fusion protein (operably linked). The limitation of a "kit" in the preamble of claim 29 connotes nothing more than a collection of items, and US 5,672,508 taught the instant claimed collection of a nucleic acid encoding p27 gene and a catheter for the practice of the invention as taught by US 5,672,508.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 29-35, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of US 6,110,744 or US 5,672,508 each in view of US 5,328,470.

The claims are drawn to a kit (composition) comprising a nucleic acid encoding p27 gene and a catheter, which may be a single balloon catheter or a double balloon catheter. The nucleic

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acid is contained in a viral particle expression vector, and the composition may also comprise a liposome. The expression vector may comprise a second gene which may be a fusion protein (operably linked).

Each of US 6,110,744 or US 5,672,508 taught the invention as described above in the rejections under 35 USC 102. The catheter was taught to be useful to deliver the desired recombinant nucleic acid encoding a p27 protein to the cells of a blood vessel to treat restenosis.

Each of US 6,110,744 or US 5,672,508 did not teach that the catheter was a single balloon or double balloon catheter.

US 5,328,470 taught a single and a double balloon catheter for the direct delivery of recombinant nucleic acids encoding genes to the walls of blood vessels.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of each of US 6,110,744 or US 5,672,508 with the teachings of US 5,328,470 to produce the instant invention because US 5,328,470 taught the single and double balloon catheters were used for delivering recombinant nucleic acids encoding genes for treating restenosis.

One of ordinary skill in the art would have been motivated to combine the teachings of each of US 6,110,744 or US 5,672,508 with the teachings of US 5,328,470 to produce the instant invention because the nucleic acid encoding a p27 gene is taught in the instant specification to be delivered to the wall of blood vessels, and US 5,328,470 taught the use of a single balloon or double balloon catheter was desirable and useful to deliver recombinant genes to the walls of a

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blood vessel in order to treat organ specific locations in an animal. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of US 6,110,744 or US 5,672,508 with US 5,328,470.

12. Claims 29-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,110,744 or US 5,672,508 with US 5,328,470 as applied to claims 29-35, 39 and 40 above, and further in view of US 6,218,372.

The claims are drawn to the invention as described above, and also to the nucleic acid encoding p27 where the nucleic acid also encodes a cytotoxic protein, which may be a fusion protein with p27. p27 may be operatively linked to the gene encoding the cytotoxic protein which may be thymidine kinase, cytosine deaminase or nitric oxide synthetase.

Each of US 6,110,744 or US 5,672,508 with US 5,328,470 taught the invention as described above and that the gene encoding p27 is recited as a useful equivalent to a gene encoding p21 in a method of treating restenosis.

Each of US 6,110,744 or US 5,672,508 with US 5,328,470 did not teach that the nucleic acid encoding p27 may also encode a cytotoxic protein, which may be a fusion protein with p27 nor where the gene encoding p27 may be operatively linked to the gene encoding the cytotoxic protein which may be thymidine kinase, cytosine deaminase or nitric oxide synthetase.

US 6,218,372 taught (see especially columns 2-6 and the claims) a nucleic acid encoding a p21 gene and a balloon catheter where the p21 gene was operatively linked to a cytotoxic

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thymidine kinase gene or cytosine deaminase gene, which may be fusion protein, where the nucleic acid may be a viral expression vector in a liposome, in a method of treatment of restenosis

It would have been obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of each of US 6,110,744 or US 5,672,508 with US 5,328,470 with the teachings of US 6,218,372 to produce the instant invention because each of US 6,110,744 or US 5,672,508 taught that p27 may be used as an equivalent for p21 in a method of treatment of restenosis.

One of ordinary skill in the art would have been motivated to combine the teachings of each of US 6,110,744 or US 5,672,508 with US 5,328,470 with the teachings of US 6,218,372 to produce the instant invention because US 6,218,372 taught that a fusion gene of p21 and thymidine kinase results in the useful and desirable reduction of intimal hyperplasia in the blood vessel in a method of treatment of restenosis and each of US 6,110,744 or US 5,672,508 taught that the gene encoding p21 may be used as an equivalent to the gene encoding p27 in a method of treating restenosis. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of US 6,110,744 or US 5,672,508 with US 5,328,470 and US 6,218,372.

Thymidine kinase, cytosine deaminase or nitric oxide synthetase are listed as equivalents for the practice of the method of treating restenosis in the instant specification. Therefore, it would have been an obvious choice within the purview of one of ordinary skill in the art to use

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any one of thymidine kinase, cytosine deaminase or nitric oxide synthetase in the method of treating restenosis.

Conclusion

13. Certain papers related to this application are ***welcomed*** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.

Examiner

March 16, 2002

